

IRB Name

Date

Model Subject Consent

[this is only a model—tailor to your study]

Project Title:

Principal Investigator:

Description of the Study. Why You? You are being asked to participate in a research study. If you participate you will be asked a series of questions by an interviewer and you will give blood to help find causes in DNA for [disease X]. DNA is a chemical molecule in every person's body that shows everything that is inherited biologically. In the DNA researchers will look for genes affecting [disease X]. You are being asked to be in the study because you or a member of your family is or was in treatment for those problems. About [X number] of people will be in the study. It is voluntary. You do not have to do it. If you are in treatment and you do not do the study, your treatment will go on in the usual way.

What will Happen? If you agree to be in this study, these things will happen: (or if you are in treatment, your care will be changed in the following ways:)

- 1) If you agree to participate about 3 tablespoons of blood will be removed by putting a needle into your vein. This is the standard method used to take blood for tests. You will feel minor pain when the needle goes into the vein. A bruise may form at the site. This takes about 5 minutes.
- 2) If this blood test does not work, you may be asked to do the test one more time in the future.
- 3) [The researchers will ask some of your relatives to give blood in the same way] if applicable.
- 4) The researchers will send to the Repository funded by the National Institutes of Health the information that you and your family gave, and also your blood cells (WITHOUT YOUR NAME OR OTHER IDENTIFIERS).
- 5) The National Institutes of Health will collect the DNA, plasma, and cells from your blood and store them permanently in a Repository.
- 6) They will take DNA from those cells when requested.
- 7) They will give your information, and DNA from your cells, (WITHOUT YOUR NAME OR OTHER IDENTIFIERS) to leading researchers around the world who are trying to learn what causes [disease X]. The researchers will keep your information secret. They agree to never try to find out who you are.

Are There any Risks or Discomforts?

- 1) One risk is a break in secrecy. You or your relatives were asked questions about very private things, like drug use. The researchers know that it could be bad if the wrong people got that information, so they do several things to keep this a secret, and those things are discussed below.
- 2) Another risk is that someone could learn about your DNA makeup if they got the information from this study. Therefore, the researchers will only release your DNA and information about you (WITHOUT YOUR NAME OR OTHER IDENTIFIERS) only to qualified researchers.
- 3) DNA tests can show family relationships (who is related to whom). Therefore, the researchers will not discuss family DNA relationships with you or anyone else.
- 4) There may be some discomfort during the blood draw and a risk for bruising.

Will This Help You? You will not get any health benefit from participating in this research study, and there are risks, as mentioned above. The blood test is not a treatment for [disease X] or any disorder.

Who Pays for It? Does It Cost You Anything? Do You Get Paid? All money for this study comes from the National Institute on Drug Abuse and the National Institutes of Health, a federal agency. It will not cost you any money. You will be paid [\$X] for your time and trouble.

Scientists who get your DNA and medical information may work with a private company. Such companies have a financial interest in using information found from studying DNA. This includes developing commercial products that may later help others by improving the diagnosis and treatment of various medical problems. These companies may patent products or sell discoveries based on this research. Some of the scientists who study your DNA and medical information may get some financial benefit from this work. There are no plans to provide any compensation to you or your heirs should this occur.

Can You Get Out of the Research If You Want To? You do not have to do the study. You can stop being in the study without affecting any care that you would receive or without losing any benefits to which you may be entitled. Also, the researchers may withdraw you from the study at any time they feel that continuing might harm your health. You can stop future studies of your DNA by writing that to the researchers. Then they will destroy your DNA.

Is This a Test for a Genetic Disease? No. Researchers do not yet know of any gene that makes [disease x] problems worse. There is no normal or abnormal result to this test. The DNA is used for research purposes only.

Who Owns the DNA That I Donate? The DNA will belong to the National Institutes of Health, a federal agency. If studies of your DNA resulted in a commercial product, you would not gain or lose any money from it.

Can You Get the Test Results? You cannot get individual results from this study. Neither can your family, your physician, nor your insurance company, nor anyone else except a qualified researcher. No results of this DNA research will be used to make any medical decision or judgment about you or any member of your family. However, information might become available in the future regarding prevention or treatment of some genetic influence on [disease x], which you or your relatives may be at risk. If so, the researchers will make a reasonable effort to contact you to ask whether you want that information from them.

How Secret Is It? Who Will Know What About Me? Information about you may be seen by (1) this institution or (2) other health researchers.

1) This Institution:

- a. They keep information with your name on it under lock and key, or in password protected computers in locked rooms with burglar alarms. Your name will not appear on the survey answer sheets. Your answers will be identified by code numbers and not by your name. That way you cannot be identified and your information stays secret. Your physician/investigator will treat your identity with professional standards of confidentiality. Information from this study may be published in medical journals, but your identity will not be revealed.
- b. Researchers here got a Certificate of Confidentiality from the U.S. Government. This Certificate is not an endorsement by the government, but it protects the Researchers from being forced to release information that identifies you, even under a court order or subpoena. However, there are a few things that researchers will report to the proper authorities:
 - i. If they learn that there may have been child abuse or neglect.
 - ii. If they learn about threats of physical violence against people.
 - iii. If the researchers' judgment is that you may harm others if information is not released.

The researchers also may give information about you to others for these reasons:

- iv. If you tell the researchers in writing to release certain information.

- v. If information is needed by medical personnel treating you in an emergency.
- vi. If you commit or threaten to commit a crime at the program or against someone working for the program.
- vii. If the researchers' judgment is that you may harm yourself if information is not released.

Also, because this research is paid for by the U.S. Government, government officials and this Institution's Institute Review Board may review records that identify you. However, these agencies and researchers make every attempt to keep secret all information that identifies you.

2) Other Health Researchers:

- a. This Institutions researchers will send your information and your blood cells WITHOUT YOUR NAME OR OTHER IDENTIFIERS to the National Institutes of Health in Bethesda, MD. The National Institutes of Health will give your DNA and your information WITHOUT YOUR NAME OR OTHER IDENTIFIERS to qualified scientists around the world.

Will Researchers Use My Information and DNA for Other Genetic Studies? By initialing below I can choose whether researchers will use my information and DNA just for studies of [disease X] and related medical problems, OR whether they can use the information and DNA for any kind of genetics study.

Put your initials on only ONE line below:

_____ Researchers can use my information and DNA only for genetic studies of [disease X] or related medical problems

_____ Researchers can use my information and DNA for any kind of genetic research.
I may be re contacted (re-consented) for future studies:
Yes or No (circle one)

What if I Get Hurt by the Research? If you are hurt by this research we will provide medical care if you want it, but you will have to pay for the care that is needed. You will not be paid for any other loss as a result of the injury, such as loss of wages, or pain and suffering. Further information can be obtained by calling Dr. [PI] at [phone number].

What If I Have Questions? You will receive a copy of this consent/assent form. Please ask questions about any part of this research or this consent/assent either now or in the future. You can direct your questions to [PI] at [phone number]. If you have questions regarding your rights as a research subject, please call [IRB] Office at [phone number].

Who Gives Permission? If you are a minor, you cannot participate unless both you and your parent or guardian give permission. The project will be explained to your parent or guardian in the same way that it is being explained to you.

AUTHORIZATION: I have read this paper about the study or it was read to me. I know what will happen, both the possible good and bad (benefits and risks). I choose to be (or have my child) in the study. I know I (or my child) can stop being in the study and I (or my child) will still get the usual medical care. I will get a copy of this consent form.

Space for appropriate signatures and dates:

1. Subject's signature
2. Parent or guardian (if subject is a minor)
3. Who explained the consent form to the subject
4. Principal investigator.